Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone. 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2936521

August 2, 2002

Gino Barsanti, CEO
Race Street Foods, Inc.
1130 Olinder Court
San Jose, CA 95122

WARNING LETTER

Dear Mr. Barsanti:

On January 16, 23, 24, and 30, 2002, we inspected your seafood processing facility, located at 1130 Olinder Court, San Jose, California. FDA organoleptic field examination conducted on January 16 and 23, 2002 detected decomposition in the fishery products listed below. All of the above FDA field examination results were confirmed by check organoleptic examinations by a second analysts. Accordingly, the following products were adulterated within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (the Act) in that they consisted in whole or in part of a decomposed substance

- 17 of 18 fillets of mahi mahi
- 1 of 2 tuna loins
- 1 of 3 tuna loins
- 3 of 4 swordfish

We acknowledge that you voluntarily destroyed [redacted] lbs of mahi mahi on January 23, 2002 However, we note from records of the previous FDA inspection in August 2000 that decomposition in fish is a recurring problem at your firm. Decomposition is a result of inadequate temperature control. We recommend that you address the problem by assuring that your suppliers have stored and transported the fishery products and that you receive and store the fishery products at temperatures at or below 40°F

In addition, we found that you had serious deviations from the seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) These deviations caused your scombroid fish species and Dungeness crab to be adulterated within the meaning of section 402(a)(4) of the Act in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may have been rendered

injurious to health. You may find the Act and the seafood HACCP regulations through links in FDA's home page at www fda gov. See attached handout on how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001. The deviations are as follows:

1. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However,

   a. Your firm's HACCP plan for scombroid fish lists monitoring procedures at the receiving critical control point that are not adequate to control histamine formation in scombroid fish. Since your firm is a secondary processor, you must assure that lots you receive have been adequately chilled throughout shipment. Your HACCP plans state that you will monitor temperatures. Monitoring internal temperatures is considered an appropriate procedure when transport time is less than 4 hours. For longer transportation periods, FDA has determined that this method does not provide adequate assurance of continuous chilling for an entire lot throughout shipment. Current FDA guidelines suggest:

   - Monitoring the adequacy of ice or cooling media surrounding products during shipment or storage;

   OR

   - Monitoring temperatures by temperature data recorders;

   OR

   - Using time/temperature integrators during shipment.

   b. Your firm's HACCP plans for Scombroid Fish and Dungeness Crabs (Cooked, Ready-to-Eat) list monitoring procedures at the storage critical control point that are not adequate to control histamine formation and pathogen growth. Your HACCP plans listed that you will check temperatures. In addition to visually monitoring temperatures, you must also have a method of assuring that scombroid fish and ready-to-eat products are maintained continuously at safe temperatures As with extended transport times, FDA has determined that intermittent temperature checks cannot provide adequate assurance of safety Our investigator observed that your firm has installed a 24-hour high temperature alarm system with the alarm set to go off at 40°F in your cooler. That preventative measure should be added to your plan, in addition to your visual temperature checks [redacted] day

2 Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate to comply with 21 CFR 123 7(b). However, your corrective action plans for scombroid species at the receiving and storage critical control points to control histamine and Dungeness Crabs (cooked, ready-to-eat) at the receiving and storage critical control points to control pathogen growth was not adequate. The corrective action, "Ugly," was listed as the disposition for the products This does not adequately describe what will be done to and how you will handle product that has been exposed to temperatures exceeding your critical limit In addition, your plan should include any other decision-making steps that you use,

such as, "Add ice to products and evaluate time/temperature exposures" or "Analytical testing."

FDA suggests that you refer to the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001 for examples of suggested corrective actions for temperature critical limits deviations designed to prevent unsafe fish from entering commerce.

At the conclusion of the inspection, the deviations were listed on Form FDA 483 (Inspectional Observations) and discussed with Stephen P. Barsanti, Vice President, Operations. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act and the seafood HACCP regulations.

Over six months have elapsed since FDA inspection which should have been sufficient time to correct the violations. We may take further action if you have not corrected these violations. For instance, we may move to seize your products and/or enjoin your firm from operating.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the deviations conveyed to you by FDA at the close of the inspection. Your response should outline the specific things you have done and are doing to correct the above-listed deviations. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you have not completed all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations

Your response should be directed to. Ms. Harumi Kishida, Compliance Officer, U S Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070 If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District